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TITLE: Acceptance of Referral for Cancer Risk Counseling in
Clinical Populations: Variables Predicting Follow-up at a
Cancer Genetics Program

PRINCIPAL INVESTIGATOR: Suzanne O'Neill, M.S., M.A.

CONTRACTING ORGANIZATION: University of Pittsburgh
Pittsburgh, Pennsylvania 15260

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13. ABSTRACT (<i>Maximum 200 Words</i>) This study was designed to demonstrated the utility of brief quantitative risk assessment in a breast biopsy clinic setting as a method of referral to cancer risk counseling. We are examining factors that influence the decision to undergo cancer risk counseling after the referral is made. Computerized risk assessment was performed on 120 women undergoing breast biopsy. Questionnaires measuring knowledge and attitudes about breast cancer, cancer risk counseling, and genetic testing were completed, and psychological assessments were done. Fifty-three percent had risk levels warranting referral and were followed to assess referral uptake. Although only one woman followed through with a referral appointment, 46% stated that they would definitely consider genetic counseling in the future. Primary reasons cited for declining referral were receipt of sufficient risk information from the brief risk assessment (40%) or from their doctors (49%), perceived "low risk" (40%), and no family history of breast cancer (31%). Objective risk, as calculated by statistical models may not be a sufficient motivation for seeking cancer risk counseling at a genetic-based program. Subjects cited a precipitating event such as a cancer diagnosis as a primary motivating factor, therefore the study has been modified and is continuing in a diagnosed treatment population.				
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Introduction

Comprehensive breast cancer risk assessment using a synthesis of statistical models, pedigree analysis, detailed medical and exposure histories, and empiric research findings has traditionally been done in cancer genetic counseling and research settings. Clinically, enumeration of risk parameters varies and may or may not result in referral to specialists in comprehensive risk assessment. This study demonstrated use, in a clinical setting, of a brief risk assessment based on computerized models to identify and refer women who might benefit from a more comprehensive risk assessment, and examined the factors that influence referred women to follow up with cancer risk counseling. One hundred and twenty women have been recruited in a breast biopsy clinic and the study has now been modified to include the affected clinical treatment population. Recruitment in surgical oncology, medical oncology, and radiation oncology clinics is ongoing. We expect to provide a better understanding of the motivations that lead women to use cancer risk counseling in order to foster development of more effective clinical referral strategies and more widespread use of cancer risk counseling.

Annual Summary

From Approved Statement of Work

Task 1. To finalize preparations for patient interviews

- a. *Preparation and approval of Institutional Review Board proposal and consent document (months 1-3)*

We anticipated a lengthy process in obtaining all necessary approvals, thus we began the process early. Proposal was approved by the Breast Cancer Research Oversight Committee of Magee-Womens Hospital on October 1, 1998, the University of Pittsburgh Cancer Institute Protocol Review Committee on November 11, 1998, and the Magee-Womens Hospital Institutional Review Board on April 13, 1999

- b. *Modification of computerized risk program to include Berry-Aguilar- and Shattuck-Eidens models (months 1-3)*

Modification was completed on May 24, 1999

- c. *Consultation with clinical staff of CBP and CGP to review protocols and incorporate concerns (months 2-3)*

Protocol was presented to staff members and logistics finalized.

- d. *Finalize compilation of behavioral measures instruments for administration to our population (month 3)*

Questionnaires were revised as requested by approval committees cited above. Formatting and printing were completed.

Task 2. To identify, through brief breast cancer risk assessment, women undergoing biopsy who are at increased risk for breast cancer and refer them to the Cancer Genetics Program for comprehensive risk assessment and possible genetic testing. (months 4-19)

- a. *Interview biopsy patients (estimated at 10 per week), recruit participants, administer pre-BRA questionnaires, perform BRA, and initiate referrals to CGP (ongoing, months 4-15)*

Identification of potential study candidates began on May 25, 1999, and recruitment began on June 1, 1999. Due to a shift in allocation of patients between the two breast biopsy sites of the University of Pittsburgh Cancer Institute (Magee-Womens Hospital Scott Williams Breast Center and the UPCI Montefiore Hospital) it was feasible to recruit only at the Magee-Womens Hospital site.

We recruited 120 women between June 1 and Dec 21 of 1999. Our original recruitment goal was 260 women over the course of 12 months, therefore we considered recruitment levels satisfactory. Recruitment was temporarily halted in January 2000, pending results of an interim data analysis. (see Task 4 part a. and Addendum)

Referral rates were higher than anticipated. The referral criterion was a 10-year Gail model risk twice that of the age-dependent population risk. Sixty-three of the 120 women who participated had risk levels that met the referral criteria and were referred.

b. Track referral uptake at CGP (ongoing, months 4-18)

All new patient appointments made at the Cancer Genetics program were screened to identify study participants. Only one referred subject followed up with a consultation visit to the CGP.

c. Administer second questionnaire and psychological measures, perform cancer risk counseling (including comprehensive risk assessment) at CGP (ongoing, months 4-19)

As stated above, only one woman followed up with a consultation at the CGP. The remaining referred subjects were contacted, by telephone, to complete a second questionnaire assessing reasons for declining follow-up appointment, and a second psychological assessment. Thirty of the sixty-three referred women completed the second interview as of January 15, 2000. Because of poor referral uptake, we suspended recruitment and undertook an interim data analysis in January 2000 to reevaluate the protocol.

Task 3. To identify outcomes of biopsy and genetic testing for mutational status (months 4-21)

a. Obtain biopsy results from medical records (ongoing, months 4-16)

Original estimates were that 20-30% of biopsy outcomes would be positive. Actual outcomes were slightly less than expected:

Malignant Cancer Dx	9%
In Situ Cancer Dx (DCIS, LCIS)	10%

b. Obtain genetic testing results from CGP (ongoing, months 5-21)

No subjects had genetic testing through the CGP as of June 1, 2000.

Task 4. To analyze predictors of CGP referral uptake, and finalize reports and dissertation (months 20-22)

a. Statistical analyses will be performed (month 20-21)

The original protocol was designed to compare two groups of subjects—women referred to the CGP who subsequently followed through on that referral by making an appointment for a consultation, and women referred to the CGP who declined to follow-up. After six months of recruitment it became apparent that almost all of the referred subjects belonged to the latter group. Thus we undertook an interim data analysis in January 2000.

Preliminary evidence obtained during follow-up interviews on over 30 subjects indicated that most women were not averse to genetic counseling, rather that they wanted to wait until “something else happened” before seeking consultation. Many stated that if their biopsy had been positive (i.e., resulted in a cancer diagnosis) they would certainly explore cancer risk counseling. We had not previously known of this timing effect. Therefore we applied for a protocol modification to transfer the study to the population for which “something” has happened, the diagnosed treatment population. Unfortunately, approvals for this modification took an extraordinarily long period of time, during which recruitment was suspended. We are now recruiting women at several different points in the treatment continuum, from

original diagnosis to completion of chemotherapy or radiation therapy. We expect to be able to answer our original questions more effectively utilizing the treatment population, and are especially interested in a comparison of the two populations in regard to optimal timing of the genetic referral.

b. Final report and doctoral thesis will be prepared (months 21-22)

Due to the delay in approval for the protocol modification, the timeline for the final report and completion of the thesis is now estimated to be May 1 2001-June 30, 2001. We will be requesting an extension of funding to cover additional graduate student stipend/salary support.

Addendum:

Modification of Protocol

Acceptance of referral for cancer risk counseling in a population of women undergoing breast biopsy: Variables predicting follow-up at a cancer genetics program

To

Acceptance of referral for cancer risk counseling in clinical populations: Variables predicting follow-up at a cancer genetics program.

In January of 2000, after the interim analysis and consultation with Drs. Wendy Rubinstein and Victor Vogel (my principal thesis advisors) and the other members of my thesis committee, it was proposed that the original hypothesis would best be addressed by transferring recruitment to the breast cancer treatment population. We did not anticipate that this modification would be difficult to implement or would result in significant delay in the completion of the project. Supervising personnel at the new recruitment sites were contacted and agreed to the proposal, and the directors of both the radiation oncology and surgical oncology divisions agreed to be co-investigators.

We requested an expedited approval for the modification because the changes involved were minor and posed no additional risk to subjects. The Magee-Womens Hospital Institutional Review Board approved this modification on January 29 (only 5 days after submission) and stated "The requested revision dated January 21, 2000 involves modifying the list of investigators as well as modifying both the consent and protocol to change the subject population to be recruited. This type of revision qualifies for expedited review under FDA and NIH (OPPR) regulations."

The modification involved a change in the recruitment population from women undergoing breast biopsy to women undergoing breast cancer treatment. This was the only substantive change in the protocol and modification of the proposal and informed consent document involved only "wording" changes to reflect the affected status of the new subject population. There was no increased risk to subjects involved and there was originally no budgetary or time-line changes.

We submitted the request to the DOD on February 14, 2000. After numerous delays purportedly caused by the shortage of reviewers due to the influx of new grant applications, we finally received a response from Dr. Angela Howard of the Army's Human Subjects Protection Office requesting additional information and response to reviewers' questions on March 25, 2000. We sent a detailed response on April 4. We received no response until April 12, when we were advised by Dr. Howard that she would not be able to read the materials for another week. The modification was again reviewed on May 8, and tentative approval (pending another review of DOD requested revisions) by the MWH IRB was requested. On June 1, 2000 the MWH approved the DOD-requested modifications and documents were submitted to the DOD. Final approval from the DOD was given on June 14.

Although we understood that the modification would necessitate an extension of the time required to complete this study, we did not anticipate a 4-month delay for approval. As a doctoral student, this translates into the loss of an entire semester of recruitment time. We will need to request additional funding from the DOD in order to complete the project, as the award was the only student stipend support that was budgeted for.

Note: Recruitment resumed under the revised protocol on June 26, 2000 in the medical oncology clinic. As of today, we have recruited 43 subjects, 21 of whom have received referrals due to increased risk. Four subjects have already followed up by making appointments for consultation at the CGP.

Additional training activities:

I have attended numerous seminars, lectures, and research talks at the University of Pittsburgh and participate in a weekly multidisciplinary breast cancer case conference. In addition I have attended the following scientific meetings:

MARHGN regional conference Philadelphia PA	Sept 1999
American Society of Human Genetics, San Francisco CA	Oct 1999 (funded by DOD)
Intercultural Cancer Council, Washington DC	Feb 2000
American Society of Clinical Oncology, New Orleans	May 2000
Univ. of Pitt. Cancer Institute annual retreat Johnstown PA	Jul 2000

Appendix A

Key Research Accomplishments

- Recruited 120 female subjects having breast biopsy at the Comprehensive Breast Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Performed computerized risk assessment, administered questionnaires
- Referred 63 subjects to Cancer Genetics Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Provided genetic counseling consultation to one follow-up patient
- Recontacted 36 referred patients to administer questionnaires ascertaining reasons for declining genetic counseling referral
- Completed preliminary statistical analyses of demographics, breast cancer and genetic attitudes and knowledge, and psychological measures
- Submitted two abstracts based on findings
- Submitted modification of study proposal to transfer protocol to the diagnosed breast cancer treatment population (February 2000)
- Received local IRB and DOD Human Review Board approval for modification (June 2000)
- Recruitment begun on June 26, 2000 in the surgical oncology, medical oncology, and radiation oncology divisions of the Comprehensive Breast Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- 43 subjects recruited as of August 10, 2000

Appendix B

Reportable Outcomes**Abstracts Submitted and Accepted:**

Brief breast cancer risk assessment at the time of breast biopsy O'Neill SM, Peters JA, Feingold E, Ferrell RE, Vogel VG, Rubinstein WS.

Abstract # 1381 50th Annual Meeting of the American Society of Human Genetics, October 3-7, Philadelphia, PA.

Emotional Disturbance at the Time of Breast Biopsy: Is This a Teachable Moment? O'Neill, Suzanne M., Davison, Deborah, Rubinstein Wendy S, Vogel Victor G.

Abstract# 216 23rd Annual San Antonio Breast Cancer Symposium Dec 6-10 San Antonio, Texas.

Employment Applied for:

February 2000 NCI-99-1718A Genetic Counselor NCI division of Clinical Genetics

Advanced to qualified applicant pool-not selected

Appendix C

Abstracts Submitted**Abstract # 1381 50th Annual Meeting of the American Society of Human Genetics, October 3-7 2000, Philadelphia, PA.**

Brief breast cancer risk assessment at the time of breast biopsy O'Neill SM, Peters JA, Feingold E, Ferrell RE, Vogel VG, Rubinstein WS. Comprehensive Breast Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Cancer Genetics Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Dept of Human Genetics, University of Pittsburgh, Pittsburgh, PA

Referral of high risk women to cancer genetic counseling services is unstandardized in general clinical populations, and little is known about the factors that influence women to follow-up with such referrals. A brief quantitative breast cancer risk assessment using computerized statistical models may be a useful method for identification of referral candidates, but information is needed about the breast cancer patient's attitudes regarding timing of, or interest in, the genetic counseling intervention.

This study followed 100 women attending a comprehensive breast program for fine needle, core, and stereotactic breast biopsies. A brief breast cancer risk assessment was done using the Gail and Claus models, questionnaires measuring knowledge, attitudes, and feelings about breast cancer, cancer risk counseling, and genetic testing were completed, and psychological assessments using the Profile of Mood States (POMS) and the Impact of Events Scale (IES) were done. Subjects with a calculated risk \geq twice the population risk were offered referrals to the Cancer Genetics Program (CGC) for comprehensive risk assessment and counseling. Referred subjects were contacted at 3-6 months post-biopsy to assess intention to follow-up with the CGP referral.

The majority of the study population was relatively young (mean =48) and of relatively high socioeconomic status, with 67% having at least some college and 70% having annual incomes above \$40,000. Almost all had health insurance (96%) and 92% reported a strong or moderately strong support system. Thirty seven percent reported a first or second degree relative with breast cancer and 53% had risk levels warranting referral. The mean Gail 10yr risk was 3.9%. Only two women had mutation carrier probabilities above 10%. In contrast to previous studies on risk perception, 85% of women in this population estimated their risk to be at or below average. Although only one woman followed through with a referral appointment, 46% stated that they would consider genetic counseling in the future, while 28% said they were not sure. The primary reason for declining referral was that subjects had obtained enough information about their risk from the brief risk assessment (40%) or from their doctors (49%). Forty percent cited "low risk" and 31% cited no family history as reasons for not following up on the referral.

Objective risk, as calculated by statistical models may not be a sufficient motivation for seeking cancer risk counseling at a genetic-based program. Although a large percentage of women indicated they definitely would or might seek such counseling in the future, many indicated that they would wait for some precipitating event, such as another biopsy or request of an offspring. This suggests that immediacy of threat may have a strong influence on referral uptake. However, for those women at increased risk, information and education is provided at a possible "teachable moment" and may have an influence on future behavior, either in the surveillance arena or in eventual participation in genetic counseling.

Appendix C: continued

Abstract# 216 23rd Annual San Antonio Breast Cancer Symposium Dec 6-10 2000, San Antonio, Texas.

Emotional disturbance at the time of breast biopsy: Is this a teachable moment? *O'Neill SM, Davison D, Vogel VG, Rubinstein WS. Comprehensive Breast Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Cancer Genetics Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA

It is assumed that breast biopsy is an anxiety-producing event for most women. However, it has been shown that moderate anxiety can be a motivating factor in assuming proactive health behaviors, such as increased screening and surveillance, and that a primary self-reported need of women undergoing breast biopsy is information and education about their future risk. This study followed 100 women attending a comprehensive breast program for fine needle, core, and stereotactic breast biopsies. In addition to questionnaires measuring breast cancer knowledge, attitudes, and feelings, subjects completed two psychological assessments; the Profile of Mood States (POMS) and the Impact of Events Scale (IES). A breast cancer risk assessment was also done using the Gail and Claus models.

Subjects were relatively young (mean=48y), predominantly Caucasian (95%), college-educated (50%), and married (71%), with 75% reporting a very strong support system. Thirty seven percent reported a first or second degree relative with breast cancer. The mean total mood disturbance score on the POMS was 16, a score higher than the normative scores reported for psychiatric outpatients. Highest scores were reported for the tension/anxiety (8), fatigue (5.1), and confusion (4.8) dimensions. The mean score on the IES for intrusive thoughts and cognitive avoidance relating to the breast biopsy were 11, and 10.9 respectively; scores approaching those of actual cancer patients. Follow-up administrations of the POMS and IES at 3-6 months post-biopsy resulted in a return to normal for most women. Women who received negative biopsy results indicated that they "did not want to think about breast cancer anymore". While time of biopsy may not be optimal for presenting complex educational information, referral algorithms outlining next-step scenarios may be optimally presented at this time.



DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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FORT DETRICK, MD 21702-5012

REPLY TO
ATTENTION OF

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15 May 03

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